UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/687,951	10/13/2000	Jeffrey L. Cleland	GEN02-002-US	8871

25226 7590 07/17/2008
MORRISON & FOERSTER LLP
755 PAGE MILL RD
PALO ALTO, CA 94304-1018

EXAMINER	
KAM, CHIH MIN	
ART UNIT	PAPER NUMBER
1656	
MAIL DATE	DELIVERY MODE
07/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/687,951	CLELAND ET AL.	
	Examiner	Art Unit	
	CHIH-MIN KAM	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20,22,23,25-29,31,33,34,36,40-43 and 45-73* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20,22,23,25-29,31,33,34,36,40-43 and 45-73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/10/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 20, 22-23, 25-29, 31, 33, 34, 36, 40-43 and 45-73 are pending.

Applicants' amendment filed April 10, 2008 is acknowledged. Applicants' response has been fully considered. Claims 20, 22, 27, 29, 31, 33, 34, 36 and 40-43 have been amended, and new claims 45-73 have been added. Therefore, claims 20, 22-23, 25-29, 31, 33, 34, 36, 40-43 and 45-73 are examined.

Withdrawn Claim Rejections - 35 USC § 112

2. The previous rejection of claims 20, 22-23, 25-29, 31, 33, 34, 36, 40-43 under 35 U.S.C. 112, first paragraph, written description, is withdrawn in view of applicants' amendment to the claim, and applicants' response at page 12 in the amendment filed April 10, 2008.

New Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 20, 22-23, 25-29, 31, 36, 40-43, 45-66 and 68-73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claims 20, 22-23, 25-29, 31, 36, 40-43, 45-66 and 68-73 are indefinite because of the use of the term "a derivative thereof". The term cited renders the claim indefinite, it is not clear what structure the derivative has, and how different the derivative is from the parent compound, hyaluronic acid. Claims 23, 25-29, 31, 36, 40-43, 45-47, 49-66 and 68-73 are included in the

rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

5. Claim 29 is indefinite because of the use of the term "a tumor necrosis factor derivative", "a CD protein", "a portion of an antibody", "a fragment of gp120", "a fragment of gp160" or "a Fab fragment". The term cited renders the claim indefinite, it is not clear what structure the derivative has, and how different the derivative is from the parent compound, tumor necrosis factor; what is "CD protein"; which fragment or portion the term "a portion of an antibody", "a fragment of gp120", "a fragment of gp160" or "a Fab fragment" refers to.

6. Claim 49 is indefinite because the claim recites a method for administering a pharmaceutical formulation of claim 20, while claim 20 is a method of administering a biologically active agent.

7. Claim 59 is indefinite because of the use of the term "CD-3; CD-4; CD-8; CD-19". The term cited renders the claim indefinite, it is not clear what the term represents. A fully spelled out word should be indicated in the first occurrence.

Maintained Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 22-23, 25-29, 31, 33, 34, 36, 42, 43, 45-47, 50-59 and 67-73 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22-24 and 26-44 of co-pending application 11/614,462 (based on the amendment filed 4/9/08). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 22-23, 25-29, 31, 33, 34, 36, 42, 43, 45-47, 50-59 and 67-73 in the instant application disclose a injectable formulation comprising: (a) an injection vehicle comprising hyaluronic acid or a derivative thereof dissolved in a physiological buffer at a concentration of about 0.01 to about 3 percent weight per volume; and (b) particles comprising: (i) a first component that is a biologically active agent; and (ii) a second component that is a biocompatible polymeric matrix, wherein the concentration of the particles is about 100 mg/mL to about 500 mg/mL of formulation, and further wherein the hyaluronic acid or a derivative thereof is at a concentration sufficient to inject the particle through a 23-gauge or smaller bore needle; and the specification indicates the invention also provide the related kits comprising articles of manufacture (e.g., a container) including the injection vehicles and formulation (page 15, line 23-page 16, line 6). This is obvious variation in view of claims 22-24 and 26-44 of the co-pending application which disclose a kit comprising: (a) an injection vehicle comprising hyaluronic acid or a derivative thereof dissolved in a physiological buffer at a concentration of about 0.01 to about 3 percent weight per volume; and (b) particles comprising: (i) a first component that is a biologically active agent; and (ii) a second component that is a biocompatible polymeric matrix, wherein (a) and (b) are dispersed in the same or separate containers adapted for simultaneous administration of (a) and (b) to an animal, and wherein the concentration of the particles is about 100 mg/mL to about 500 mg/mL of formulation formed by

combining the injectable vehicle and the particles. Both sets of claims are directed to an injectable formulation comprising an injectable vehicle and particles comprising an active agent; or a related kit comprising the injectable formulation. Thus, claims 22-23, 25-29, 31, 33, 34, 36, 42, 43, 45-47, 50-59 and 67-73 in present application and claims 22-24 and 26-44 in the co-pending application are obvious variations of an injectable formulation comprising an injectable vehicle and particles comprising an active agent; or a kit comprising the injectable formulation.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicants indicate that because neither application has been allowed, it is currently not possible to determine whether a terminal disclaimer needs to be filed to remove the obviousness type double patenting rejection. Applicants will address this issue when claims of one or both applications are found allowable (page 12 of the response).

Applicants' response has been considered, since applicants do not address the issue at this time, the rejection is maintained.

Conclusion

9. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chih-Min Kam/
Primary Examiner, Art Unit 1656

CMK
July 14, 2008